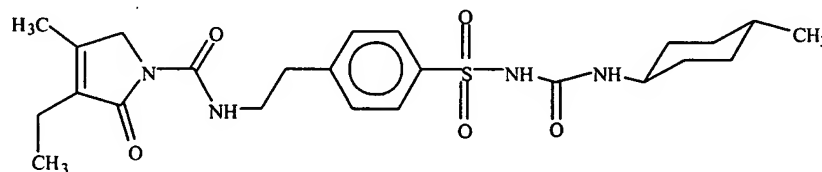


**We claim**

1) A process for the preparation of *trans*-3-Ethyl-2,5-dihydro-4-methyl-N-[2-[4-[[[(4-methylcyclohexyl)amino]carbonyl]amino]sulfonyl]phenyl]ethyl]-2-oxo-1*H*-pyrrole-1-carboxamide, a compound of the formula 1,

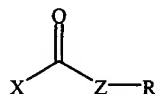


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**Formula 1**

comprising,

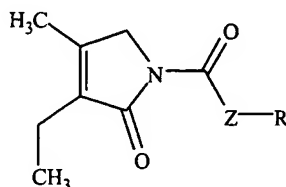
a) reacting 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2,



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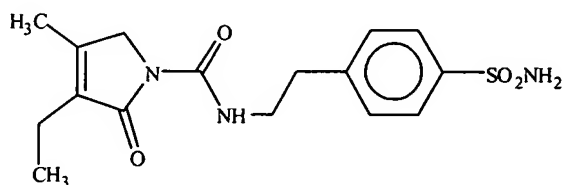
**Formula 2**

to obtain a compound of formula 3,

**Formula 3**

b) reacting a compound of formula 3 with 4-(2-Aminoethyl)benzene sulfonamide to obtain 4-[2-(3-Ethyl-4-methyl-2-carbonyl pyrrolidine amido)ethyl]benzene sulfonamide, a compound of formula 4,

15

**Formula 4**

c) and further reacting the compound of formula 4 with *trans*-4-methylcyclohexyl isocyanate to obtain the compound of formula 1,

wherein,

X is halogen, nitroaryl or haloaryl,

5 Z is O, S or NY, wherein Y is C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>1</sub>-C<sub>5</sub>-haloalkyl, aryl or aralkyl, and

R is aryl or heteroaryl, where aryl or heteroaryl radical is unsubstituted or substituted by one or more radicals from the group consisting of nitro, halogen, cyano, azido, haloalkyl, CO-R<sup>1</sup>, SR<sup>2</sup>, SO-R<sup>3</sup> and SO<sub>2</sub>-R<sup>4</sup>,

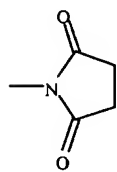
10 R<sup>1</sup> is H, C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>2</sub>-C<sub>5</sub>-alkenyl, C<sub>2</sub>-C<sub>5</sub>-alkynyl, C<sub>1</sub>-C<sub>5</sub>-alkoxy or C<sub>2</sub>-C<sub>5</sub>-alkenoxy,

R<sup>2</sup> is C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>2</sub>-C<sub>5</sub>-alkenyl, C<sub>2</sub>-C<sub>5</sub>-alkynyl, C<sub>1</sub>-C<sub>5</sub>-haloalkyl or C<sub>2</sub>-C<sub>5</sub>-haloalkenyl,

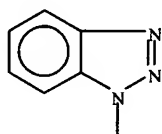
R<sup>3</sup> is C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>2</sub>-C<sub>5</sub>-alkenyl, C<sub>2</sub>-C<sub>5</sub>-alkynyl, C<sub>1</sub>-C<sub>5</sub>-haloalkyl or C<sub>2</sub>-C<sub>5</sub>-haloalkenyl,

15 R<sup>4</sup> is C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>2</sub>-C<sub>5</sub>-alkenyl, C<sub>2</sub>-C<sub>5</sub>-alkynyl, C<sub>1</sub>-C<sub>5</sub>-haloalkyl or C<sub>2</sub>-C<sub>5</sub>-haloalkenyl, or

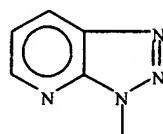
the moiety represented below by P, Q, S or T.



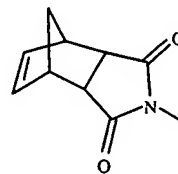
(P)



(Q)

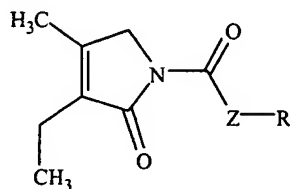


(S)



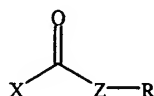
(T)

20 2) A process for the preparation of a compound of formula 3,



**Formula 3**

comprising reacting 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2,



**Formula 2**

5 wherein,

X is halogen, nitroaryl or haloaryl,

Z is O, S or NY, wherein Y is C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>1</sub>-C<sub>5</sub>-haloalkyl, aryl or aralkyl, and

R is aryl or heteroaryl, where aryl or heteroaryl radical is unsubstituted or substituted by one or more radicals from the group consisting of nitro, halogen, cyano, azido, haloalkyl, CO-R<sup>1</sup>, SR<sup>2</sup>, SO-R<sup>3</sup> and SO<sub>2</sub>-R<sup>4</sup>,

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R<sup>1</sup> is H, C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>2</sub>-C<sub>5</sub>-alkenyl, C<sub>2</sub>-C<sub>5</sub>-alkynyl, C<sub>1</sub>-C<sub>5</sub>-alkoxy or C<sub>2</sub>-C<sub>5</sub>-alkenoxy,

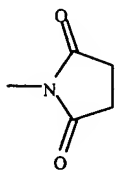
R<sup>2</sup> is C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>2</sub>-C<sub>5</sub>-alkenyl, C<sub>2</sub>-C<sub>5</sub>-alkynyl, C<sub>1</sub>-C<sub>5</sub>-haloalkyl or C<sub>2</sub>-C<sub>5</sub>-haloalkenyl,

15

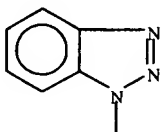
R<sup>3</sup> is C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>2</sub>-C<sub>5</sub>-alkenyl, C<sub>2</sub>-C<sub>5</sub>-alkynyl, C<sub>1</sub>-C<sub>5</sub>-haloalkyl or C<sub>2</sub>-C<sub>5</sub>-haloalkenyl,

R<sup>4</sup> is C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>2</sub>-C<sub>5</sub>-alkenyl, C<sub>2</sub>-C<sub>5</sub>-alkynyl, C<sub>1</sub>-C<sub>5</sub>-haloalkyl or C<sub>2</sub>-C<sub>5</sub>-haloalkenyl, or

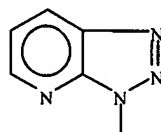
the moiety represented below by P, Q, S or T.



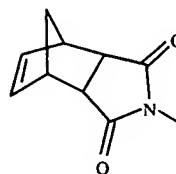
(P)



(Q)



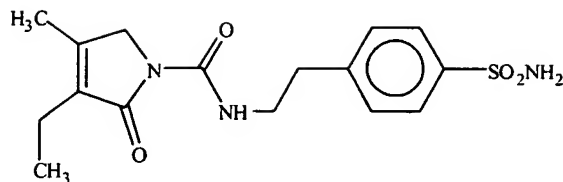
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(T)

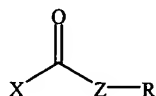
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3) A process for the preparation of a compound of formula 4,

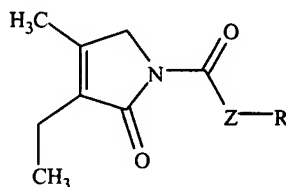
**Formula 4**

comprising,

- a) reacting 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2,

**Formula 2**

to obtain a compound of formula 3,

**Formula 3**

- b) reacting a compound of formula 3 with 4-(2-Aminoethyl)benzene sulfonamide to obtain 4-[2-(3-Ethyl-4-methyl-2-carbonyl pyrrolidine amido)ethyl]benzene sulfonamide, a compound of formula 4,

wherein,

X is halogen, nitroaryl or haloaryl,

Z is O, S or NY, wherein Y is C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>1</sub>-C<sub>5</sub>-haloalkyl, aryl or aralkyl and

R is aryl or heteroaryl, where aryl or heteroaryl radical is unsubstituted or substituted by one or more radicals from the group consisting of nitro, halogen, cyano, azido, haloalkyl, CO-R<sup>1</sup>, SR<sup>2</sup>, SO-R<sup>3</sup> and SO<sub>2</sub>-R<sup>4</sup>,

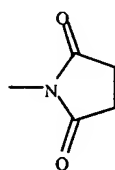
R<sup>1</sup> is H, C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>2</sub>-C<sub>5</sub>-alkenyl, C<sub>2</sub>-C<sub>5</sub>-alkynyl, C<sub>1</sub>-C<sub>5</sub>-alkoxy or C<sub>2</sub>-C<sub>5</sub>-alkenoxy,

R<sup>2</sup> is C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>2</sub>-C<sub>5</sub>-alkenyl, C<sub>2</sub>-C<sub>5</sub>-alkynyl, C<sub>1</sub>-C<sub>5</sub>-haloalkyl or C<sub>2</sub>-C<sub>5</sub>-haloalkenyl,

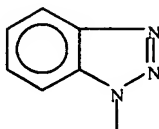
$R^3$  is  $C_1$ - $C_5$ -alkyl,  $C_2$ - $C_5$ -alkenyl,  $C_2$ - $C_5$ -alkynyl,  $C_1$ - $C_5$ -haloalkyl or  $C_2$ - $C_5$ -haloalkenyl,

$R^4$  is  $C_1$ - $C_5$ -alkyl,  $C_2$ - $C_5$ -alkenyl,  $C_2$ - $C_5$ -alkynyl,  $C_1$ - $C_5$ -haloalkyl or  $C_2$ - $C_5$ -haloalkenyl, or

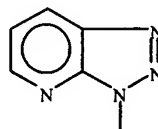
5 the moiety represented below by P, Q, S or T.



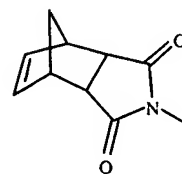
(P)



(Q)

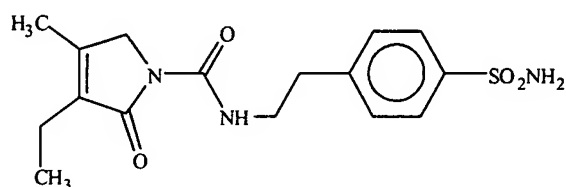


(S)



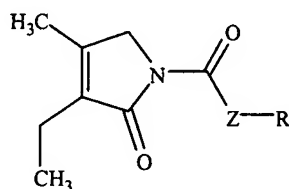
(T)

4) A process for the preparation of a compound of formula 4,



10 **Formula 4**

comprising reacting a compound of formula 3



15 **Formula 3**

with 4-(2-Aminoethyl)benzene sulfonamide to obtain 4-[2-(3-Ethyl-4-methyl-2-carbonylpyrrolidine amido)ethyl]benzene sulfonamide, a compound of formula 4,

wherein,

Z is O, S or NY, wherein Y is  $C_1$ - $C_5$ -alkyl,  $C_1$ - $C_5$ -haloalkyl, aryl or aralkyl and R is aryl or heteroaryl, where aryl or heteroaryl radical is unsubstituted or substituted by one or more radicals from the group consisting of nitro, halogen, cyano, azido, haloalkyl,  $CO-R^1$ ,  $SR^2$ ,  $SO-R^3$  and  $SO_2-R^4$ ,

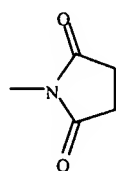
$R^1$  is H,  $C_1$ - $C_5$ -alkyl,  $C_2$ - $C_5$ -alkenyl,  $C_2$ - $C_5$ -alkynyl,  $C_1$ - $C_5$ -alkoxy or  $C_2$ - $C_5$ -alkenoxy,

$R^2$  is  $C_1$ - $C_5$ -alkyl,  $C_2$ - $C_5$ -alkenyl,  $C_2$ - $C_5$ -alkynyl,  $C_1$ - $C_5$ -haloalkyl or  $C_2$ - $C_5$ -haloalkenyl,

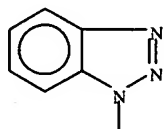
5  $R^3$  is  $C_1$ - $C_5$ -alkyl,  $C_2$ - $C_5$ -alkenyl,  $C_2$ - $C_5$ -alkynyl,  $C_1$ - $C_5$ -haloalkyl or  $C_2$ - $C_5$ -haloalkenyl,

$R^4$  is  $C_1$ - $C_5$ -alkyl,  $C_2$ - $C_5$ -alkenyl,  $C_2$ - $C_5$ -alkynyl,  $C_1$ - $C_5$ -haloalkyl or  $C_2$ - $C_5$ -haloalkenyl, or

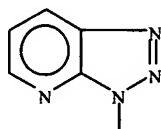
the moiety represented below by P, Q, S or T.



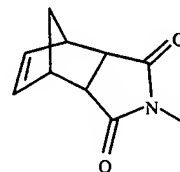
(P)



(Q)



(S)

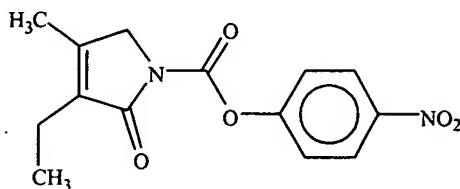


(T)

5) The process as claimed in claim 4 wherein the compound of formula 4 is further reacted with *trans*-4-methylcyclohexyl isocyanate to obtain the compound of formula 1.

15 6) The process as claimed in claim 1, 2 or 3 wherein the reaction of 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2, is carried out in presence of an organic base.

7) The process as claimed in claim 1, 2 or 3 wherein 3-Ethyl-4-methyl-3-pyrrolidin-2-one is reacted with the compound of formula 2, wherein Z is O and R is 4-nitrophenyl,

**Formula 3a**

to obtain a compound of formula 3a.

8) The process as claimed in claim 1 comprising,

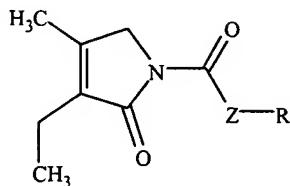
- a) reacting 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2, wherein Z is O and R is 4-nitrophenyl, to obtain a compound of formula 3a,
  - b) reacting the compound of formula 3a with 4-(2-Aminoethyl)benzene sulfonamide to obtain 4-[2-(3-Ethyl-4-methyl-2-carbonyl pyrrolidine amido)ethyl]benzene sulfonamide, a compound of formula 4,
  - c) and further reacting the compound of formula 4 with *trans*-4-methylcyclohexyl isocyanate to obtain the compound of formula 1.
- 9) The process as claimed in claim 3 comprising,
- a) reacting 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2, wherein Z is O and R is 4-nitrophenyl, to obtain a compound of formula 3a,
  - b) reacting the compound of formula 3a with 4-(2-Aminoethyl)benzene sulfonamide to obtain 4-[2-(3-Ethyl-4-methyl-2-carbonyl pyrrolidine amido)ethyl]benzene sulfonamide, a compound of formula 4.
- 10) The process as claimed in claim 4 comprising reacting a compound of formula 3, wherein Z is O and R is 4-nitrophenyl with 4-(2-Aminoethyl)benzene sulfonamide to obtain 4-[2-(3-Ethyl-4-methyl-2-carbonyl pyrrolidine amido)ethyl]benzene sulfonamide, a compound of formula 4.
- 11) The process as claimed in claim 5, wherein the compound of formula 4 is prepared by a process comprising reacting a compound of formula 3, wherein Z is O and R is 4-nitrophenyl, with 4-(2-Aminoethyl)benzene sulfonamide to obtain 4-[2-(3-Ethyl-4-methyl-2-carbonyl pyrrolidine amido)ethyl]benzene sulfonamide, a compound of formula 4.
- 12) The process as claimed in claim 1, 2 or 3 wherein the reaction of 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2, is carried out in presence of an organic base selected from the group consisting of 4-dimethylaminopyridine; 4-pyrrolidinopyridine; diisopropylethylamine, tetramethylguanidine; 1,8-diazabicyclo[5.4.0]undec-7-ene; 1,5-diazabicyclo [4.3.0] non-5-ene; 2,6-lutidine and picolines.

- 13) The process as claimed in claim 1, 2 or 3 wherein the reaction of 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2 is carried out in presence of an acid scavenger compound.
- 14) The process as claimed in claim 1, 2 or 3 wherein the reaction of 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2 is carried out in presence of an acid scavenger compound selected from the group consisting of trialkylamines, pyridine, sodium carbonate and potassium carbonate.
- 15) The process as claimed in claim 1, 2 or 3 wherein the reaction of 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2 is carried out in presence of an acid scavenger compound characterised in that the acid scavenger compound is triethylamine.
- 16) The process as claimed in claim 1, 2 or 3 wherein the reaction of 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2 is carried out in presence of an organic base and an acid scavenger compound, characterised in that the organic base is 4-dimethylaminopyridine and the acid scavenger compound is triethylamine.
- 17) The process as claimed in claim 1, 2 or 3 wherein the reaction of 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2 is carried out in presence of a solvent selected from the group consisting of aliphatic or aromatic hydrocarbons, ethers, nitriles and amides.
- 18) The process as claimed in claim 1, 2 or 3 wherein the reaction of 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2 is carried out in a chlorinated hydrocarbon solvent.
- 19) The process as claimed in claim 1, 2 or 3 wherein the reaction of 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2 is carried out in dichloromethane.
- 20) The process as claimed in claim 1, 2 or 3 wherein the reaction of 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2 is carried out at a temperature between the range of about 0°C to about 35°C for about 8 to about 15 hours.



- 21) The process as claimed in claim 1, 3 or 4 wherein the reaction of a compound of formula 3 with 4-(2-Aminoethyl)benzene sulfonamide to obtain 4-[2-(3-Ethyl-4-methyl-2-carbonyl pyrrolidine amido)ethyl]benzene sulfonamide, a compound of formula 4, is carried out in the presence of a solvent selected from the group consisting of aliphatic or aromatic hydrocarbons, ketones, nitriles and amides.
- 22) The process as claimed in claim 10 wherein the reaction is carried out in acetone.
- 23) The process as claimed in claim 1, 3 or 4 wherein the reaction of a compound of formula 3 with 4-(2-Aminoethyl)benzene sulfonamide to obtain 4-[2-(3-Ethyl-4-methyl-2-carbonyl pyrrolidine amido)ethyl]benzene sulfonamide, a compound of formula 4, is carried out at a temperature between the range of about 35°C to about 80°C for about 0.5 to about 20 hours.
- 24) The process as claimed in claim 2, comprising reacting 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2, wherein X is Cl, Z is O and R is 4-nitrophenyl, to obtain 3-Ethyl-4-methyl-2,5-dihydro-N-(4-nitrophenyloxy carbonyl)-pyrrole-2-one, a compound of formula 3a, having purity of greater than 99%.
- 25) The process as claimed in claim 24, wherein the compound of formula 3a is further reacted with 4(2-Aminoethyl)benzene sulfonamide to obtain 4-[2-(3-Ethyl-4-methyl-2-carbonyl pyrrolidine amido)ethyl]benzene sulfonamide, a compound of formula 4 having purity of greater than 99%.
- 26) The process as claimed in claim 1 comprising,
- a) reacting 3-Ethyl-4-methyl-3-pyrrolidin-2-one with a compound of formula 2, wherein X is Cl, Z is O and R is 4-nitrophenyl, to obtain a compound of formula 3a,
  - b) reacting the compound of formula 3a with 4-(2-Aminoethyl)benzene sulfonamide to obtain 4-[2-(3-Ethyl-4-methyl-2-carbonyl pyrrolidine amido)ethyl]benzene sulfonamide, a compound of formula 4,
  - c) and further reacting the compound of formula 4 with *trans*-4-methylcyclohexyl isocyanate to obtain the compound of formula 1 having purity of greater than 99%.

27) The intermediate compound of formula 3,



**Formula 3**

wherein,

Z is O, S or NY, wherein Y is C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>1</sub>-C<sub>5</sub>-haloalkyl, aryl or aralkyl, and R is aryl or heteroaryl, where aryl or heteroaryl radical is unsubstituted or substituted by one or more radicals from the group consisting of nitro, halogen, cyano, azido, haloalkyl, CO-R<sup>1</sup>, SR<sup>2</sup>, SO-R<sup>3</sup> and SO<sub>2</sub>-R<sup>4</sup>,

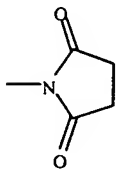
R<sup>1</sup> is H, C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>2</sub>-C<sub>5</sub>-alkenyl, C<sub>2</sub>-C<sub>5</sub>-alkynyl, C<sub>1</sub>-C<sub>5</sub>-alkoxy or C<sub>2</sub>-C<sub>5</sub>-alkenoxy,

R<sup>2</sup> is C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>2</sub>-C<sub>5</sub>-alkenyl, C<sub>2</sub>-C<sub>5</sub>-alkynyl, C<sub>1</sub>-C<sub>5</sub>-haloalkyl or C<sub>2</sub>-C<sub>5</sub>-haloalkenyl,

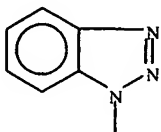
R<sup>3</sup> is C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>2</sub>-C<sub>5</sub>-alkenyl, C<sub>2</sub>-C<sub>5</sub>-alkynyl, C<sub>1</sub>-C<sub>5</sub>-haloalkyl or C<sub>2</sub>-C<sub>5</sub>-haloalkenyl,

R<sup>4</sup> is C<sub>1</sub>-C<sub>5</sub>-alkyl, C<sub>2</sub>-C<sub>5</sub>-alkenyl, C<sub>2</sub>-C<sub>5</sub>-alkynyl, C<sub>1</sub>-C<sub>5</sub>-haloalkyl or C<sub>2</sub>-C<sub>5</sub>-haloalkenyl, or

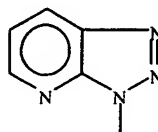
the moiety represented below by P, Q, S or T.



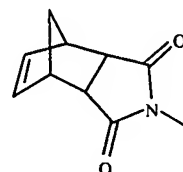
(P)



(Q)



(S)

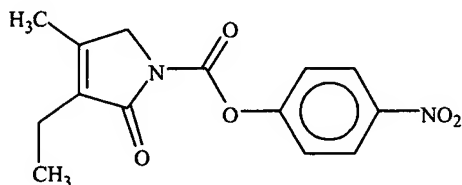


(T)

28) The intermediate compound of formula 3, as claimed in claim 27 wherein Z is O and R is aryl or the moiety represented by (P), (Q), (S) or (T), characterised in that aryl is phenyl substituted with one or more radicals selected from nitro, halo, cyano, 4-trifluoroalkyl, 2,4-bis(trifluoroalkyl) or 2,6-bis(trifluoroalkyl).

- 29) The intermediate compound of formula 3, as claimed in claim 27, wherein Z is O and R is selected from phenyl substituted with 4-nitro, 2,4-dinitro, 2,6-dinitro, 4-halo, 2,4-dihalo, 2,6-dihalo, 4-trifluoromethyl, 2,4-bis(trifluoromethyl) or 2,6-bis(trifluoromethyl).

- 5 30) The intermediate compound of formula 3a.



**Formula 3a**

- 31) The intermediate compound of formula 3, as claimed in claim 27, wherein Z is O and R is represented by the moiety (P), (Q), (S) or (T).
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